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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/798,692

03/11/2004

Mark W. Becker

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07/25/2006

GILEAD SCIENCES INC
333 LAKESIDE DR
FOSTER CITY, CA 94404

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/798,692 | Applicant(s) BECKER ET AL. | |
| | Examiner Dr. Kailash C. Srivastava | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06.29/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 34-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>07/06/2006</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicants' amendment and remarks filed 29 June 2006 in response to Office Action mailed 26 May 2006 is acknowledged and entered.
2. In view of Applicants remarks and arguments filed 29 June 2006 and the substance of the interview with Applicants' Representative, Mr. Max D. Hensley on 06 July 2006 (See interview Summary attached); the finality of the Office Action mailed 24 January 2006 is hereby withdrawn.
3. In view of the Interview with Mr. Max D. Hensley on 06 July 2006, previous Office actions are hereby vacated and the prosecution is re-opened in this application.
4. Examiner has fully and carefully considered Applicants' arguments and remarks filed 13 April 2006 and 29 June 2006, however, in view of the vacated previous Office Action cited *supra*, those remarks are moot.

Claims Status

5. Claims 1-33 stand cancelled.
6. Claims 38 and 41 have been amended.
7. Claims 34-47 are pending.

Election /Restriction

8. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Group I, consisting of claim 34-40 and 42--47 drawn to a composition, classified under Class 530, subclass 300, for example.
 - Group II, consisting of claim 41, drawn to a method, classified under Class 424, subclass 78.29, for example.

Inventions are Independent Or Distinct

9. Invention in Group I is related to invention in Group II as product and use thereof. The

inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. The method of invention encompassed in Group II invention can be accomplished with a number of therapeutic products available in the market place. Similarly, product of invention in Group I for e.g., has numerous materially different uses than those claimed. For e.g., to simply inhibit a virus in a host.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. For example in search strategy for invention in group I one has to incorporate key words describing different specific features of the composition. To search for the invention encompassed in Group II invention; one will have to incorporate a different set of key words for the prophylaxis. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

Species Election

10. This application contains claims directed to different compositions comprised of a variety of ingredients. Therefore, if the applicants elect anyone of Groups I-II above, the applicants must also make election of species by electing a single species from each of the following categories:

- i. Only one compound having a structure among those claimed in one of Claims 34-37

ii. Only one concentration of the compound claimed in Claims 42-47.

11. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR §1.143).

12. In accordance with 37 CFR §1.499, applicant is required that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a group including that of a species. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

13. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.


In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §

103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.


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Patent Examiner
Art Unit 1655
(571) 272-0923

July 17, 2006


CHRISTOPHER R. TATE
PRIMARY EXAMINER